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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,789	09/10/2003	Christopher J. Stenland	B185 1210.1 (MSC 8015)	5573

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EXAMINER

HORNING, MICHELLE S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,789

Applicant(s)

STENLAND ET AL.

Examiner

Michelle Horning

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 23-30, and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to communication filed on 6/01/2006. It is further noted that the Restriction sent out by the examiner established a 3 month period for Applicant's response. The status of the claims is as follows: claims 1-36 are pending, claims 1-18, 23-30 and 32-36 are under examination and claims 19-22 and 31 are drawn to non-elected species.

Claim Objection

Claim 24 is objected to because of the following informalities: "50 g/l" should be g/L. Appropriate correction is required.

Claim Rejections

35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The

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term "metal oxides" in claims 7, 8, 9, 10, 11, 33 and 34 is used by the claims to mean "fumed silica or silicon dioxide", while the accepted term is "non-metal oxides." The term is indefinite because the specification does not clearly redefine the term. The chemical nature of silica or silicon dioxide can be further investigated using the Periodic Table (see Si).

35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7-8, 12-14, 29-30 and 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Montalto et al (Patent No.: US 6,743,899). These claims are limited to:

1. method of preparing a solution containing biological material and adding metal oxide solution, wherein the pathogenic prion proteins are reduced in the resulting solution;
2. method of 1 mentioned above with the additional step of evaluating the presence or amount of pathogenic prion proteins;
3. the biological material is a blood-derived product;

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4.the metal oxide is a fumed silica; and

5. separation of the metal oxide from the mixture via filtration, wherein the system retains particle larger than about 0.1-about 5 microns or larger than about 0.8 microns.

Montalto et al teaches all of the above limitations. Specifically, Montalto et al discloses the above method steps, including mixing SIPERNAT 50 or fumed silica with a biological material or more specifically, prion-infected lipoproteins (col. 14 and 15, under Example 2). Further, the biological material is blood-derived, specifically stemming from bovine serum (col. 14, Example 2). Following the adsorption process, the lipoproteins are filtered out using 0.45 and 1 micron filters (col. 16, Example 2). This process reduces, eliminates and/or inactivates the transmissible spongiform encephalopathy agent as evaluated by assay by titration of Golden Syrian hamsters placed on test for 17 months (col. 17, Example 2).

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-11, 15-18, 23-28 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montalto et al (Patent No.: US 6,743,899) in view of Prusiner et al (Patent No.: US 6,221,614).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

As mentioned above, Montalto et al teaches mixing SIPERNAT 50 or fumed silica with a biological material or more specifically, prion-infected lipoproteins (col. 14 and 15, under Example 2). Further, the biological material is blood-derived, specifically stemming from bovine serum (col. 14, Example 2). Following the adsorption process, the lipoproteins are filtered out using 0.45 and 1 micron filters (col. 16, Example 2). This process reduces, eliminates and/or inactivates the transmissible spongiform encephalopathy agent as evaluated by assay by titration of Golden Syrian hamsters placed on test for 17 months (col. 17, Example 2). Montalto et al do not teach modifying

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surface areas and weight ratios of silica for optimization or evaluating a sample for prion infectivity using an immunoassay, more specifically, a Western blot. Prusiner et al teach altering the weight ratio of silica to support material from 1:20 to 1:1 and modifying effective surface area to significantly remove prions from the biological fluid to undetectable levels (col. 10, lines 32-45). Further, this reference disclosed the widely used Western blot to test for the presence of prions from the blood-derived product, plasma (col. 17, Example 1).

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Montalto et al and Prusiner et al in order to sufficiently reduce prion levels and subsequently, test for the presence of prion proteins. One would have been motivated to do so to effectively remove prions from the blood-derived product. There would have been a reasonable expectation of success, given that both techniques are commonly used and based on the success of another assay taught by Montalto et al. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

CONCLUSION


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michelle Horning
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